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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,029	03/22/2000	Jacqueline Heard	MBI-0010	7823

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WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/533,029

Applicant(s)

HEARD ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 28 January 2002 for a Continued Prosecution Application (CPA) under 37 CFR § 1.53(d) as a Divisional Application based on parent Application No. 09/533,029 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restrictions

2. Applicant's election with traverse of SEQ ID NOs: 17 and 18 in Paper No. 18, filed 15 March 2002 is acknowledged. The traversal is on the ground(s) that the restriction requirement entered in the parent application carries over from the parent application (page 2 of the Remarks). The Examiner responds that MPEP § 819 clearly states that the expressed election made in the prior application in reply to a restriction requirement carries over in a continuation and not in a divisional application. The Examiner directs Applicants attention to the Preliminary Amendment filed 28 January 2002, as Paper No. 16, where Applicant states on page 1 that "applicants have filed a request for a divisional continued prosecution application (CPA) of application number 09/533,029". Hence, the requirement for restriction/election is proper.

Applicant also argues that the election is an election of species and examination of the pending claims directed to all of the claimed SEQ ID NOs would not pose an undue burden on the Examiner (pages 3-4 of the Remarks). This is not found persuasive because the claims are directed to a transgenic plant comprising a recombinant polynucleotide encoding a transcription factor, the recombinant

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polynucleotide comprising a nucleotide sequence encoding a conserved domain of a plant AP2 transcription factor and a nucleotide sequence encoding a polypeptide comprising a homologous window sequence of at least 6 consecutive amino acids selected from SEQ ID NO: 12, 18, 22, 34, 66, 82 and 96 (see claim 1). The pending claims are not directed to discrete polynucleotides but to a large, minimally defined genus of polynucleotides. Searching such a genus would pose an undue search burden on the Examiner. In addition, on page 3, lines 9-10, of Paper No. 17, mailed 15 February 2002, the Examiner clearly states that this election is not to be construed as an election of species, because each polynucleotide sequence is structurally, compositionally, and functionally unique, especially in view of the claimed invention directed to AP2 transcription factors that modulate the expression of many different genes.

The requirement is still deemed proper and is therefore made FINAL.

3. SEQ ID NOs: 12, 22, 34, 66, 82 and 96 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 18.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Claim Objections

5. Claims 17, 18, 23, 24, 28, 29 and 34 are objected to because of the following informalities: The instant claims are directed to SEQ ID NOs., non-elected in Paper No. 18. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 17-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claims 17, 23 and 28, the phrase “a conserved domain of a plant AP2 transcription factor” is indefinite because it is unclear what the metes and bounds of this limitation are. The instant specification does not define the metes and bounds the claim limitation. The specification only defines “a conserved domain” in view of SEQ ID NO: 18 in Figure 1(a), said conserved domain being relative to SEQ ID NO: 18. In addition the reference on page 8, line 1, to AP2 domain transcription factor family does not appear to be a valid reference.

At claim 17, 23 and 28, the phrase “outside of the conserved domain” is indefinite for the reason given supra. This phrase refers to an indefinite limitation and thus does not state the metes and bounds of the claimed invention.

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At claims 17, 23 and 28, the phrase "freezing, or nutrient or pathogen stress" is indefinite because of the multiple uses of the conjunction "or", it is unclear what the metes and bounds of "the plant's tolerance to...nutrient" are.

Claims 17, 18, 23, 24, 28, 29 and 34 are indefinite for being in an improper Markush format. Amendment of the claims to limit the "sequence selected" to either SEQ ID NO: 17 or 18 would obviate this rejection as discussed supra in the claim objections.

At claims 18, 24 and 29, at line 2, the phrase "a conserved domain" is indefinite. The specification only defines "a conserved domain" in view of SEQ ID NO: 18 in Figure 1(a), said conserved domain being relative to SEQ ID NO: 18. In addition, the specification is silent as to the metes and bounds of "a localization domain, an activation domain, a repression domain, an oligomerization domain and a DNA binding domain" in relation to the amino acid sequence of SEQ ID NO: 18, or a polynucleotide that encodes said amino acid sequence.

At claims 22, 27 and 33, the phrase "the nucleotide sequence is SEQ ID NO: 18" is indefinite because SEQ ID NO: 18 represents an amino acid sequence.

At claim 35, the phrase "the recombination polynucleotide comprises a conserved domain" is indefinite because it is unclear what the metes and bounds of "a DNA binding domain" is in relation to a polynucleotide and the instant invention are.

Claims 19-21, 25-26, 30-32 and 36 are indefinite for being dependent upon an indefinite claim, the limitations in said claims do not obviate the indefiniteness of the claim to which they depend.

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8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 17-36 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a transgenic plant comprising a recombinant polynucleotide encoding a transcription factor, the recombinant polynucleotide comprising a nucleotide sequence encoding "a conserved domain" of a plant AP2 transcription factor and a nucleotide sequence encoding a polypeptide comprising a homologous window sequence of at least 6 consecutive amino acids of SEQ ID NO: 18 (elected invention), wherein the window sequence is outside of the conserved domain, and methods for enhancing the disease tolerance or resistance of a plant, or altering the expression levels of at least one gene in a plant comprising said recombinant polynucleotide. In addition, Applicant claims a method for enhancing the disease tolerance or resistance in a plant comprising transforming the plant with a recombinant polynucleotide comprising at least 18 consecutive nucleotides of SEQ ID NO: 17 (elected invention).

Applicant describes a putative AP2 transcription factor having the amino acid sequence of SEQ ID NO: 18 and encoded by a polynucleotide having the nucleotide sequence of SEQ ID NO: 17.

Applicant does not describe other polynucleotides encoding "a conserved domain" of a plant AP2 transcription factor and a nucleotide sequence encoding a polypeptide comprising a homologous window sequence of at least 6 consecutive amino acids of SEQ ID NO: 18, wherein the window sequence is outside of the conserved domain, or other polynucleotides comprising at least 18 consecutive nucleotides of SEQ ID NO: 17 (within the scope of the elected invention). The indefiniteness of claims 22, 27 and 33 are discussed supra. In addition, Applicant's definition of "a conserved domain" appears to be relative to SEQ ID NO: 18 and does not sufficiently describe the genus of polynucleotides to which the claims are directed.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

10. Claims 17-36 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims a transgenic plant comprising a recombinant polynucleotide encoding a transcription factor, the recombinant polynucleotide comprising a nucleotide sequence encoding "a conserved domain" of a plant AP2 transcription factor and a nucleotide sequence encoding a polypeptide comprising a homologous window sequence of at least 6 consecutive amino acids of SEQ ID NO: 18 (elected invention), wherein the window sequence is outside of the conserved domain, and methods for enhancing the disease tolerance or resistance of a plant, or altering the expression

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levels of at least one gene in a plant comprising said recombinant polynucleotide wherein expression of the recombinant polynucleotide enhances the plant's tolerance to salt, heat, drought, osmotic stress, cold, freezing, or nutrient or pathogen stress. In addition, Applicant claims a method for enhancing the disease tolerance or resistance in a plant comprising transforming the plant with a recombinant polynucleotide comprising at least 18 consecutive nucleotides of SEQ ID NO: 17 (elected invention).

Applicant does not teach that a plant transformed with a polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO: 18, can enhance the plant's tolerance to salt, heat, drought, osmotic stress, cold, freezing, or nutrient or pathogen stress. The teachings on pages 24-25 in Example VII, demonstrates that the putative NAM transcription factor of SEQ ID NO: 74 and the putative AP2 transcription factor of SEQ ID NO: 22 can confer relative resistance to *Erysiphe* and or nematode infection. The specification is silent as to the function of the putative AP2 transcription factor of SEQ ID NO: 18.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

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Applicant has provided no evidence that the putative AP2 transcription factor of SEQ ID NO: 18 can confer on a transformed plant enhanced tolerance to salt, heat, drought, osmotic stress, cold, freezing, or nutrient or pathogen stress. The art teaches that although the basic function of plant transcription factors is well established, i.e. regulating the transcription of genes, the specific function is unpredictable without empiric evidence of that specific function. The art teaches that transforming a plant with a gene encoding a heterologous transcription factor to produce a desired phenotype in the transformed plant is unpredictable (see Quattrocchio *et al* 1998, The Plant Journal, 13(4): 475-488, especially pages 475-476). Hence it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen through a myriad of polynucleotides comprising a nucleotide sequence encoding "a conserved domain" of a plant AP2 transcription factor and a nucleotide sequence encoding a polypeptide comprising a homologous window sequence of at least 6 consecutive amino acids of SEQ ID NO: 18 wherein the window sequence is outside of the conserved domain, transform a myriad of plants with the identified polynucleotides and determine which identified polynucleotide will confer on a transgenic plant tolerance to salt, heat, drought, osmotic stress, cold, freezing, or nutrient or pathogen stress.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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12. Claims 17-36 are rejected under 35 U.S.C. § 102(b) as being anticipated by Martin *et al* 1997 (WO 97/47183).

The indefiniteness of claims 22, 27 and 33 are discussed supra.

Martin discloses a method and a transgenic plant comprising a recombinant polynucleotide encoding a transcription factor, the recombinant polynucleotide comprising a nucleotide sequence encoding "a conserved domain" of a plant AP2 transcription factor and a nucleotide sequence encoding a polypeptide comprising a homologous window sequence of at least 6 consecutive amino acids of SEQ ID NO: 18, wherein the window sequence is outside of the conserved domain and methods for enhancing the disease tolerance or resistance of a plant, or altering the expression levels of at least one gene in a plant comprising said recombinant polynucleotide wherein expression of the recombinant polynucleotide enhances the plant's tolerance to salt, heat, drought, osmotic stress, cold, freezing, or nutrient or pathogen stress (see claims 4, 8, 10, 11, 17, 18, 19 and Figure 1). Martin's SEQ ID NO: 4, found on pages 17-18, comprises a "window sequence of at least 6 consecutive amino acids" outside of "the conserved domain" of Applicant's SEQ ID NO: 18 of -- WGDLPK--. In addition, Martin's SEQ ID NO: 4 comprises at least 18 consecutive nucleotide of Applicant's SEQ ID NO: 17. Hence, Martin has previously disclosed all of the claim limitations.

Double Patenting

13. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR § 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR § 3.73(b).

14. Claims 17-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/713,994. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 17 of the instant application is identical to SEQ ID NO: 28 of the copending application. Any claims to transformed plants of the copending application would inherently have the claimed phenotype of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 17-36 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/934,455. Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 17 of the instant application is identical to SEQ ID NO: 32 of the copending application. Any claims to transformed plants of the copending application would inherently have the claimed phenotype of the instant application.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

David H. Kruse, Ph.D.
24 May 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

